January 23, 2024

Chairperson Liz Krueger
Senate Finance Committee
172 State Street, Capitol
Building Room 416 CAP
Albany, NY 12247
Via financechair@nysenate.gov

Chairperson Helene E. Weinstein
Assembly Ways and Means Committee
LOB 711-A
Albany, NY 12248
Via wamchair@nyassembly.gov

RE: FY 2025 Executive Budget, Department of Health, Scheduling of Xylazine

Dear Chairperson Krueger and Chairperson Weinstein,

The American Veterinary Medical Association (AVMA) recognizes the threat of illicit xylazine as it poses grave health and safety risks to human users. However, if scheduling of xylazine happens in New York without an exemption for veterinary uses, it would drastically change the way veterinarians are able to care for their patients, creating animal welfare and human safety concerns. As you can imagine, this is a huge concern for veterinarians and livestock producers.

Xylazine is a non-narcotic veterinary sedative, analgesic, and muscle relaxant that has been approved in the United States for veterinary use since 1972. It is used across veterinary medicine and is especially important when working with cattle, horses, zoo, wildlife, and laboratory species to facilitate safe medical evaluation, treatment, and surgical care.

Sedation of fractious and large animals with xylazine is critical to keeping people and animals safe. This drug is needed for safe cattle handling and when performing procedures such as disbudding/dehorning, treating leg or hoof injuries, and handling obstetrical complications such as pulling calves, performing Caesarian sections, and correcting uterine torsions. Xylazine can also be used to immobilize injured animals at processing plants before euthanizing and disposal in compliance with USDA humane handling requirements. There is no practical alternative for sedation in cattle. Limiting veterinary access to this critical drug will jeopardize animal welfare and human safety.

There are currently only two manufacturers of xylazine for veterinary use in the United States. Xylazine is a low-volume generic drug that generates little revenue for manufacturers and we do not believe there is a significant diversion from the legitimate veterinary distribution channel. Increased regulations on legitimate xylazine to address illicit xylazine will result in supply chain disruptions or eliminate the product from the market. If xylazine is scheduled as a controlled substance without an exemption for veterinary use, there is a very real risk that it will cease to be available in New York because of the increased regulatory burden and costs for the manufacturers and distributors. It is our understanding that one of the manufacturers has already ceased making the product until there is more regulatory clarity and uniformity between states. This leaves one manufacturer currently providing product to the entire U.S. market.

The veterinary community is not taking the drug epidemic and the role xylazine plays lightly. Discussions with the U.S. Drug Enforcement Administration (DEA) and lawmakers led to the introduction of the bipartisan, bicameral Combating Illicit Xylazine Act. This legislation would engage and equip the DEA with tools to combat illicit xylazine while maintaining veterinarians' access and ability to legitimately use this critical animal sedative. The legislation is supported by a long list of stakeholders, including us and the New York State Veterinary Medical Society (NYSVMS).

On December 12, 2023, key elements of the Combating Illicit Xylazine Act were incorporated into the Support for Patients and Communities Reauthorization Act (H.R. 4531 or SUPPORT Act) passed the House with overwhelming bipartisan support on a vote of 386-37. This bill would schedule xylazine as a Schedule III drug and exempt the FDA-approved animal drug from scheduling. This would provide DEA enforcement tools necessary to address illicit xylazine while preserving legitimate veterinary access. There is precedent for this, as Congress has taken this approach before with another animal drug.

We respectfully request that any provision related to scheduling of xylazine exempt use in legitimate veterinary practice.

<u>Suggested language:</u>

Xylazine as a Schedule III substance except when it is used in any of the following manners:

1. Dispensing or prescribing for, or administration to, a nonhuman species of a drug containing Xylazine that has been approved by the Secretary of Health and Human Services under section 512 of The Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 360b).
2. Dispensing or prescribing for, or administration to, a nonhuman species that is permissible under section 512(a)(4) of The Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 360b(a)(4)).
3. The manufacturing, distribution or use of Xylazine as an active pharmaceutical ingredient for manufacturing an animal drug approved under section 512 of The Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 360b or issued an investigation use exemption under subsection (j) of § 512.)
4. The manufacturing, distribution or use of a Xylazine bulk chemical for pharmaceutical compounding by licensed pharmacists or veterinarians.

5. Another use approved or permissible under The Federal Food, Drug, and Cosmetic Act.

The AVMA continues to work with Congress, the Administration and Federal agencies on solutions to address this pressing public health issue while maintaining veterinarians' access and use of this critical veterinary drug. A federal solution is anticipated soon, until then we appreciate your consideration of this necessary amendment for all New York veterinarians and the animals under their care.

Sincerely,

About the AVMA

As one of the oldest and largest veterinary medical organizations, with more than 104,000 member veterinarians worldwide engaged in a wide variety of professional activities and dedicated to the art and science of veterinary medicine, the mission of the AVMA is to lead the profession by advocating for its members and advancing the science and practice of veterinary medicine to improve animal health and welfare and human health.